Three-Port Versus Standard Four-Port Laparoscopic Cholecystectomy: a Randomized Controlled Clinical Trial in a Community-Based Teaching Hospital in Eastern Nepal

Manoj Kumar, MS, DNB, MNAMS, MRCS (Edin), Chandra Shekhar Agrawal, MS, Rakesh Kumar Gupta, MS

ABSTRACT

Objectives: With increasing surgeon experience, laparoscopic cholecystectomy has undergone many refinements including reduction in port number and size. Three-port laparoscopic cholecystectomy has been reported to be safe and feasible in various clinical trials. However, whether it offers any additional advantages remains controversial. This study reports a randomized trial that compared the clinical outcomes of 3-port laparoscopic cholecystectomy versus conventional 4-port laparoscopic cholecystectomy.

Methods: Seventy-five consecutive patients who underwent elective laparoscopic cholecystectomy were randomized to undergo either the 3-port or the 4-port technique. Four surgical tapes were applied to standard 4-port sites in both groups at the end of the operation. All dressings were kept intact until the first follow-up 1 week after surgery. Postoperative pain at the 4 sites was assessed on the first day after surgery by using a 10-cm unscaled visual analog scale (VAS). Other outcome measures included analgesia requirements, length of the operation, postoperative stay, and patient satisfaction score on surgery and scars.

Results: Demographic data were comparable for both groups. Patients in the 3-port group had shorter mean operative time (47.3 ± 29.8 min vs 60.8 ± 32.3 min) for the 4-port group (P=0.04) and less pain at port sites (mean score using 10-cm unscaled VAS: 2.19 ± 1.06 vs 2.91 ± 1.20 (P=0.02). Overall pain score, analgesia requirements, hospital stay, and patient satisfaction score (mean score using 10-cm unscaled VAS: 8.2 ± 1.7 vs 7.8 ± 1.7 , P=0.24) on surgery and scars were similar between the 2 groups.

Department of Surgery, B P Koirala Institute of Health Sciences, Dharan, Nepal (all authors).

Address reprint requests to: Manoj Kumar, MS, DNB, MNAMS, MRCS (Edin), Associate Professor, Department of Surgery, B P Koirala Institute of Health Sciences, Dharan. Telephone: 00977 25 525555 2047, Fax: 00977 25 520251, E-mail: docmk 2002@vahoo.co.in

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Conclusion: Three-port laparoscopic cholecystectomy resulted in less individual port-site pain and similar clinical outcomes with fewer surgical scars and without any increased risk of bile duct injury compared with 4-port laparoscopic cholecystectomy. Thus, it can be recommended as a safe alternative procedure in elective laparoscopic cholecystectomy.

Key Words: Laparoscopic cholecystectomy.

INTRODUCTION

The first laparoscopic cholecystectomy (LC) was performed in 1987 by Phillip Mouret and later established by Dubois and Perissat in 1990.^{1,2} Since then, it has met with wide-spread acceptance as a standard procedure. Standard laparoscopic cholecystectomy is done by using 4 trocars. The fourth (lateral) trocar is used to grasp the fundus of the gallbladder so as to expose Calot's triangle. With increasing surgeon experience, laparoscopic cholecystectomy has undergone many refinements including reduction in port size.3-7 It has been argued that the fourth trocar may not be necessary, and laparoscopic cholecystectomy can be performed safely without using it. Cooperative manipulation of the surgical instruments is very important for this procedure, for exposing Calot's triangle and dissecting the gallbladder from the gallbladder bed when using the 3-port techniques. Several studies have reported that 3-port laparoscopic cholecystectomy is technically possible.3,8,9 Further, in the era of laparoscopic surgery, less postoperative pain and early recovery are major goals to achieve better patient care and cost effectiveness. Several studies have demonstrated that less postoperative pain is associated with a reduction in either size or number of ports.^{4,8–10}

We did a prospective randomized controlled clinical study to explore the feasibility of reducing port number without compromising the safety in cases of laparoscopic cholecystectomy and evaluated the real benefit associated with it in terms of pain, recovery, and patient satisfaction.

We sought to investigate the technical feasibility, safety, and benefit of 3-port laparoscopic cholecystectomy versus

standard 4-port laparoscopic cholecystectomy in our setup. Technical feasibility was defined as performance of the LC without much difficulty by using the 3-port technique. The need of a fourth port was considered a failure of the 3-port technique and the reason behind this is discussed herein.

Safety was defined as performance of the procedure without any major complications like bleeding and injury to the bile duct or any viscera.

Benefits were measured by various parameters like operative time, days of hospital stay, postoperative recovery time after discharge, days taken to return to work, cosmetic satisfaction, quantitative requirement of analgesia after surgery, and assessment of postoperative pain score using a 10-cm unscaled visual analogue score (VAS).

METHODS

We prospectively recruited into this study 75 consecutive patients aged 18 to 75 who were indicated for elective LC. Exclusion criteria included patients with acute cholecystitis with empyema gallbladder and patients who were not fit for laparoscopic surgery on anesthetic grounds. All procedures were performed by experienced specialist laparoscopic surgeons who had performed more than 100 conventional LCs and at least 20 3-port LCs prior to the study. All patients signed informed consent for the randomization and procedure.

Patients were randomized to receive either 3-port (3-port group) or conventional LC (4-port group) after satisfactory general anesthesia. An 11-mm infraumbilical port, a 10-mm subxyphoid port, and two 5-mm subcostal ports were used in 4-port LC. We adopted the single surgeon technique in the 4-port LC using zero-degree operating telescopes. In 3-port LC, an 11-mm infraumbilical port, 10-mm subxyphoid, and 5-mm subcostal ports were used. We used an operating telescope (Karl Storz 26036A zero degree, Tuttlingen, Germany) that was inserted into the infraumbilical port. Retraction of the gallbladder was done by the long grasping forceps through the 5-mm subcostal port, whereas dissection was accomplished through the 10-mm subxyphoid port. The cystic duct and cystic artery were clipped by a 10-mm multiple clip applicator in both groups. The gallbladder was retrieved through the umbilical port after the position of the operating telescope was changed. Nontransparent surgical adhesive tape was applied to the standard 4-port sites at the end of the operation in both groups. All wound dressings were kept intact until the first follow-up 1 week after surgery. Thus, all patients were blinded to the type of operation they underwent. Intramuscular injection of diclofenac 50mg was given every 8 hours for the first 24 hours for postoperative pain control. Our primary outcome measure was pain score and analgesia requirements after surgery. An independent doctor assessed the pain score by using a 10-cm unscaled visual analog scale (VAS) for each dressing site and the overall pain after 12 hours and on the first day after the operation. Several other outcome measures were used. Length of operation and operative difficulty: the operative time was recorded from the beginning of the first incision until closure of the final wound. Patient satisfaction score for surgery was assessed by an independent person who determined the satisfaction score by using a 10-cm unscaled VAS on the day of discharge. Patients were discharged on the first or second postoperative day if they had satisfactory pain control and were able to tolerate their usual diet. In case of intolerable pain, unable to consume a normal diet, or any other problem, discharge was delayed until recovery. The assessment was made by an independent specialist surgeon who did not know the type of surgery that the patient underwent. Patient satisfaction score on scars were reviewed 1 week after surgery by an independent doctor who assessed the satisfaction score for the scar by using a 10-cm unscaled VAS (0, unsatisfied; 10, very satisfied). Days of requirement of continuous oral analgesic tablet and days to return to normal activity were also noted.

Statistical Analysis

The Student t test was used to evaluate the significance of each parameter. For analysis of the visual analogue scores, which were not normally distributed, the Mann-Whitney U test was used. A P value <0.05 was considered statistically significant. Statistical Package for Social Science (SPSS) Version 11.5, (Chicago, Illinois) for Windows was used for statistical analysis.

RESULTS

From August 2004 to July 2005, 75 consecutive patients were recruited for this study. The demographic data and indications for cholecystectomy were comparable in both groups **(Table 1)**. In terms of outcome, success rate was the same in both groups **(Table 2)**. The 3-port group had a significantly shorter mean operative time than did the 4-port group (47.3 min vs. 60.8; P=0.04). There was no statistically significant difference in the number of oral analgesic tablets, postoperative hospital stay, cosmetic satisfaction, and days to return to normal work. Visual

Table 1. Demographic Data				
	Group 1 (3 Ports)	Group 2 (4 Ports)	P Value	
n	36	39		
Age (years) (mean+SD)	38.22 ± 13.67	39.13 ± 14.10	0.78	
Sex ratio (F:M)	30:6	32:7	0.52	
Race (Mongol:Aryan)	14:22	13:26	0.46	
Acute Cholecystitis	04	03		
Chronic Cholecystitis	32	36		

Table 2. Patient Outcomes					
	Group 1 (3 Ports)	Group 2 (4 Ports)	P Value		
n	36	39			
Operating Time	47.3 ± 29.8	60.8 ± 32.3	0.04		
Days of Analgesic Tab Requirement	3.6 ± 0.68	4.3 ± 1.08	0.02		
Post-op Stay (d)	1.19 ± 0.06	1.44 ± 0.17	0.39		
Days to Return to Normal Activity	4.9 ± 0.85	5.8 ± 1.95	0.16		
Success Rate	97.3%	97.5%			
VAS Score (1–10)	2.19 ± 1.06	2.91 ± 1.20	0.02		
Satisfaction Score (7 d)	8.2 ± 1.7	7.8 ± 1.7	0.24		

analog scores in the postoperative period at 12 hours were 2.19 vs 2.91(P=0.02) and at 24 hours 2.22 vs 2.44 (P=0.4) in 3-port and 4-port groups. This suggests that there is a significant difference in pain in these 2 groups in the early postoperative period, but later on, the VAS scores are close in the 2 groups showing no statistically significant difference. Mean postoperative stay in the hospital was 1.19 vs 1.44 (P=0.39) in the 3- and 4-port groups. The mean patient satisfaction score for surgery was not different between the 2 groups 7.7 ± 1.6 for the 3-port group vs. 6.3 ± 2.0 for the 4-port group; P=0.28). Similarly, there was no significant difference between the 2 groups regarding the mean patient satisfaction score for the scar on day 7 $(8.2\pm1.7 \text{ for the 3-port group vs. } 7.8\pm1.7 \text{ for the 4-port}$ group; P=0.24). The most painful port site was the umbilical port followed by the subxyphoid port in both groups. Days to return to normal activity in the 3-port and 4-port groups were 4.9 vs 5.8 (P=0.16), which was not statistically significant.

DISCUSSION

In the era of laparoscopic surgery, less postoperative pain and early recovery are major goals to achieve better patient care and cost effectiveness. Several studies demonstrated that less postoperative pain was associated with reduction in either size or number of ports.^{4,8-10} In the current study, we failed to demonstrate any difference in terms of overall pain score 24 hours after the surgery, and oral analgesic tablet requirements among the 2 groups. However, it is conceivable that less pain is associated with the site at which no incision was made and at 12 hours were 2.19 vs 2.91(P=0.02), considered to be statistically significant. The majority of procedures in this study were performed by a single surgical specialist. We had only one conversion to open cholecystectomy due to bleeding from the cystic artery in the 4-port group. No conversions were necessary in the 3-port group nor did any patient require the fourth port to complete the surgery. A similar success rate has been described in the other reported studies.3,4,10,11 We did not have any bile duct injury in any of these groups. The median hospital stay was 2 days for both groups. We believe that with defined protocols, both techniques can be safely performed. It was also interesting that the mean operative time was shorter for the 3-port LC group, which does

not correlate with previous studies.^{3,5,9} One explanation for the shorter operative time in the 3-port group is that less time was spent on the establishment and subsequent closure of the additional port. One finding that was consistently noted in this series was that 3-port laparoscopic cholecystectomy was slightly difficult to perform in long gallbladders with a long peritoneal fold. This was because the fundus of the long gallbladder repeatedly fell towards the area of dissection in Calot's triangle. However, overall results suggest that the 3-port LC technique was not difficult to master and could be safely performed by trained personnel.^{12–17}

Some surgeons have expressed concerns about the safety of the 3-port technique, arguing that it may lead to a higher percentage of the bile duct injuries. 1 However, bile duct injury can be avoided if the gallbladder is gripped at the infundibulum, retracted laterally, and dissected at the infundibulum-cystic duct junction rather than cystic ductcommon bile duct junction.2 This study has shown comparable results to those of other studies done in the past and has confirmed the safety of the procedure.3,4,18-22 However, because the size of the patient cohort in our study was small, to address these concerns requires further study with a large number of patients. Most of our patients reported high satisfaction with the surgery and the surgical scars in both groups. Although there was a higher observed satisfaction score for the 3-port LC group, this did not reach statistical significance.

CONCLUSION

It appears that the 3-port LC technique is safe and has similar clinical outcomes to those of the conventional 4-port LC, with no obvious increase in bile duct injuries, a reduced need for analgesic injections, and it can be a viable alternative in the field of minimally invasive laparoscopic cholecystectomy.

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